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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/036,681 | 11/08/2001 | David G. Barkalow | 112703-198 | 4991 |

7590 12/30/2002
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EXAMINER

SHEIKH, HUMERA N

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| ART UNIT | PAPER NUMBER |
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1615

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/036,681

Applicant(s)

BARKALOW ET AL.

Examiner

Humera N. Sheikh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002(paper no.5).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Amendment filed 10/07/02.

The claim objections for claims 17 and 18 have been withdrawn.

The 35 U.S.C. 112 second paragraph rejections for claims 1, 3, 10, 12, 15, 16 and 19 have been withdrawn by virtue of the amendment.

The 35 U.S.C. 102(b) rejections have been withdrawn.

Claims 1-19 are pending. Claims 1, 10, 12, 14-19 have been amended. No new claims have been added. Claims 1-19 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zerbe *et al.* (US Pat. No. 5, 948,430, collectively, "Zerbe") or Iwakura *et al.* (US Pat. No. 4,777,046, collectively, "Iwakura") in view of Meyers (US Pat. No. 5,433,960).

Zerbe *et al.* teach a water-soluble film composition for oral administration comprising a film-forming agent, filler and a plasticizer in the instantly claimed percentages (see reference column 2, lines 14-67); (column 3, lines 1-61) and examples.

Zerbe while teaching a film composition comprising a film-forming agent, filler and a plasticizer does not teach the particular film-forming agent, carageenan.

Meyers (US Pat. No. 5,433,960) teaches an edible film composition comprising film-forming agents - carageenan gum, bulking agents and plasticizers (see reference column 3, line 15 through col. 5, line 15); (col. 6, lines 20-38). Meyers teach that the edible water-soluble film-forming agents for use with the invention include cellulose derivatives, modified starch, maltodextrin, polyols, low calorie bulking agents, edible polymers, edible plastics and vegetable gums including guar gum, locust bean gum, *carageenan gum*, etc (col. 6, lines 20-38).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any film-forming agent, in particular, carageenan, as taught by Meyers in combination with the fillers and plasticizers of Zerbe because Meyers explicitly teaches the use of an edible film composition comprising film-forming agents, such as carageenan gum, which exhibits adhesive characteristics, in combination with bulking agents and plasticizers. The expected result would be an improved, coated edible film composition for oral administration.

Iwakura et al. teach a preparation in the form of a film for oral cavity administration comprising a film-forming agent, filler and a plasticizer in the instantly claimed percentages (see abstract) and (columns 1 and 2).

Iwakura while teaching a preparation in the form of a film for oral cavity administration comprising a film-forming agent, filler and a plasticizer, does not teach the particular film-forming agent, carageenan.

Meyers (US Pat. No. 5,433,960) teaches an edible film composition comprising film-forming agents - carageenan gum, bulking agents and plasticizers (see reference column 3, line 15 through col. 5, line 15); (col. 6, lines 20-38). Meyers teach that the edible water-soluble film-forming agents for use with the invention include cellulose derivatives, modified starch, maltodextrin, polyols, low calorie bulking agents, edible

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polymers, edible plastics and vegetable gums including guar gum, locust bean gum, *carageenan gum*, etc (col. 6, lines 20-38).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any film-forming agent, in particular, carageenan, as taught by Meyers in combination with the fillers and plasticizers of Iwakura because Meyers explicitly teaches the use of an edible film composition comprising film-forming agents, such as carageenan gum, which exhibits adhesive characteristics, in combination with bulking agents and plasticizers. The expected result would be an improved, coated edible film composition for oral administration.

Response to Arguments

Applicant's arguments filed 10/07/02 have been fully considered.

Firstly, the applicant argued regarding the 35 U.S.C. 102(b) rejections of Zerbe, Iwakura or Lazard. These arguments were considered and have been withdrawn by virtue of the amendment.

Secondly, the applicant argued regarding the 35 U.S.C. 103(a) rejections for claim 19, in that, "Zerbe does not disclose or suggest a film forming agent comprising carageenan." This argument has been fully considered, but was not found to be persuasive. Zerbe teaches a film-forming agent, filler and a plasticizer. Zerbe does not

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teach the specified natural gum, carageenan. Meyers teaches carageenan gum in an edible film composition.

The present invention is drawn to a pullulan free edible film composition comprising: a film-forming agent comprising carageenan, at least one bulk filler agent and at least one plasticizing agent.

Zerbe et al. and Iwakura et al. teach edible film compositions comprising film-forming agents, bulk fillers and plasticizers. The primary references are deficient only in the sense of the absence of the particular water-soluble gum. Meyers is relied upon to show that the prior art is well aware of the equivalency (see col. 6, lines 20-38) of edible water-soluble films and that it would be prima facie obvious to one of ordinary skill in this art to use any of the disclosed natural gums, including carageenan.

Furthermore, the applicant has not provided any scientific comparison establishing some superiority of the claimed gum (carageenan) over the teachings of the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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